

Message Text

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PAGE 01 STATE 205331

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ORIGIN HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-05 /024 R

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DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/APT/BMP:MBEAUBIEN

DHEW/OIH/MACODDING

EUR/WE:KSHIRLEY (INFO)

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R 282132Z AUG 75

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

UNCLAS STATE 205331

E.O. 11652:N/A

TAGS: ETRD, OGEN, TBIO, BE

SUBJECT: FDA ADVISORY - MISBRANDED BIOLOGICAL PRODUCT

1. FDA ADVISES THAT THE:

PRODUCT: FACTOR IX COMPLEX (HUMAN) -TWO VIALS CONTAINED
IN A BLUE AND WHITE CARDBOARD BOX; VIALS LABELED: "30
M1, DRIED, NDC 0944-0581-01 XXX FACTOR IX COMPLEX (HUMAN)
(FACTORS II, VII, IX, AND X) CAUTION FEDERAL (USA)
LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. THIS
BOTTLE CONTAINS: UNITS OF FACTOR II ACTIVITY, UNITS OF FACTOR
IX ACTIVITY (IN VIVO RECOVERABLE UNITS) - LOT NO.-
EXPIRATION DATE - HYLAND DIVISION TRAVENOL LABORATORIES,
INC. COSTA MESA, CALIF. 92626 USA AND "30 M1 SINGLE DOSE
CONTAINER STERILE WATER FOR INJECTION FOR RECONSTITUTION OF
ACCOMPANYING PRODUCT, NONPYROGENIC CAUTION:
FEDERAL (USA) LAW PROHIBITS DISPENSING WITHOUT
PRESCRIPTION. LOT NO. - HYLAND TRAVENOL LABORATORIES, INC.
COSTA MESA, CALIF. 92626 USA"

EACH CARTON CONTAINS AN INSERT ENTITLED: HYLAND FACTOR
COMPLEX (HUMAN) (FACTORS II, VII, IX, AND X, DRIED
PROPLEX." FOR INTRAVENOUS ADMINISTRATION.

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PAGE 02 STATE 205331

LOT NUMBERS INVOLVED: 0581A010A, 0581A011A (LAST THREE DIGITS AND LETTER ARE SEQUENTIAL LOT NUMBERS).

MANUFACTURER: HYLAND DIVISION TRAVENOL LABORATORIES,
LOS ANGELES, CALIF.

2. THE PRODUCT IS BEING RECALLED BECAUSE OF MISBRANDING. THE PRODUCT WAS TESTED BY THE FIRM FOR HBAG AND WAS LABELED BY THE FIRM AS BEING NEGATIVE. HOWEVER, A MORE SENSITIVE TEST (AUSRIA II) SHOWS THAT IN FACT THE PRODUCT WAS HBAG POSITIVE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

TRAVENOL LABS BELGIUM
C/O AIR EXPRESS INT'L
BRUSSELS NAT'L AIRPORT
BRUSSELS, BELGIUM
710 UNITS OF LOT 0581A010A

4. POST IS REQUESTED TO CONTACT FOREIGN CONSIGNEE TO DETERMINE IF FIRM IS FAMILIAR WITH PROBLEM. ANY QUESTION CONSIGNEE MAY HAVE REGARDING PROBLEM OR DISPOSITION OF PRODUCT SHOULD BE DIRECTED TO FIRM DIRECTLY.
INGERSOLL

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: LABELING, FOOD & DRUG REGULATIONS
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Draft Date: 28 AUG 1975
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
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Margaret P. Grafeld
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06 JUL 2006

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To: BRUSSELS
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